a) a safe and effective amount of an antimicrobial agent selected from the group consisting of stannous ion agent, triclosan, triclosan monophosphate, chlorhexidine, domiphen bromide; cetylpyridinium chloride (CPC), zinc ion agent, copper ion agent, essential oils, and mixtures thereof;

b) a safe and effective amount of an additional therapeutic agent selected from the group consisting of anti-inflammatory agents, H2-antagonists, metalloproteinase inhibitors, cellular redox modifiers, and mixtures thereof; and

c) a pharmaceutically-acceptable topical, oral carrier.

## REMARKS

The above amendments are made to more clearly define the present invention in response to the Examiner's restriction requirements. Claim 6 is further amended to correct an inadvertent transcribing error. Applicants thank the Examiner for pointing the incorrect dependency of Claim 6. Method Claim 6 is amended to properly depend from method "Claim 5" rather than composition Claim 4. No new matter is involved with these amendments to the claims and no additional claims fee is known to be due.

### Restriction Requirement

The Examiner has set a restriction requirement and election was requested from among Groups I-XIV claims (Claims 1-4) drawn to a topical oral composition comprising an antimicrobial agent and a pharmaceutically acceptable carrier and optionally, further comprising another therapeutically active agent and Groups XV-XXVII claims (Claims 5-9), drawn to a method of promoting whole body health comprising administration of a topical oral composition comprising an antimicrobial agent along with a pharmaceutically acceptable carrier and optionally, further comprising another therapeutically active agent. Election of a single disclosed species of antimicrobial agent and a single species of additional therapeutically active agent such as a specific H2 antagonist was further required.

For the purpose of complying with the election requirements, Applicants provisionally elect, with traverse, Group XVII method Claims 7-9; triclosan as the species of antimicrobial agent, H2 antagonist from among the Markush group of additional therapeutic agents recited in Claims 3 and 8; and cimetidine as the single species of H2 antagonist.

The restriction requirements are respectfully traversed herein.

The Examiner submits that the composition claims of Groups I-XIV and the method claims of Groups XV-XXVII are distinct inventions, for the reason that Groups I-XIV compositions could be used in a materially different way than claimed in Groups XV-XXVII methods. Specifically, the Examiner contends that each of the compositions as claimed can be used as an immunogen in a method of producing monoclonal antibodies as well as in a method for promoting whole body health. The Examiner further contends that the claims recite distinct species of each genus of additional therapeutically active agent and requires election of a single disclosed species of each for prosecution on the merits.

Applicants respectfully submit that the present composition claims and method claims are so closely interrelated and in order to preserve unity of invention, composition claims and the methods of use claims of said compositions should be prosecuted in the same application. The PTO examination would be simplified and duplicate searching eliminated by pursuing one as opposed to two or more applications. As the Examiner pointed out in Item 4 of the Office Action, the composition claims and method claims are related as product and process of use.

Applicants respectfully point out that the Groups I-XIV composition claims are each specifically directed to a topical oral composition, which is defined as a product which in the ordinary course of usage is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity. The present invention is specifically concerned with treating and preventing bacteria-mediated conditions in the oral cavity and thereby promoting whole body health, specifically by topically administering the present compositions to the oral cavity as opposed to systemic administration or to any other mode of administration to any other part of the body. Applicants can find no basis in the Examiner's contention that the present topical oral compositions can be used "in a materially different process" such as an "immunogen in a method of producing monoclonal antibodies". Applicants respectfully request withdrawal of the restriction requirement between composition claims and method of use claims.

Applicants also traverse the restriction requirement with respect to a species of antimicrobial agent and species of additional therapeutic agent.

The major reason for restriction requirements is the unduly burdensome effect in searching the art for a variety of distinct species. In this instance, since the present claims are directed to topical oral compositions, searching the art would involve the body of art classified under Class 424, Subclass 49 and Subclasses 50 through 58, which are indented subclasses under 424/49. Applicants respectfully point out that Classes 424/49 through 424/58 include ALL compositions which function primarily in the normal hygiene of the oral cavity regardless of form or constituents. Further the following notes are included with the class definition of 424/49.

(1) Note. A composition intended to be employed regularly in normal mouth-care is placed herein even if the composition contains ingredients of specific value in killing micro-organisms or in the treatment or prevention of specific mouth diseases or malfunctions such as pyorrhea trench mouth, gingivitis, etc.

(2) Note. Since a dentifrice or mouthwash is generally compounded of a plurality of ingredients, some of the significant kinds of ingredients have been set out in indented subclasses 50 to 58. For a particular ingredient containing composition not specifically provided for by said indents, a search through this and the indented subclasses will be necessary.

The Examiner's attention is respectfully directed particularly to Notes (1) and (2) with regard to the class definition, which clearly indicate that compositions for mouth care comprising antimicrobial agents or other agent would also be placed within 424/49 through 424/58.

Therefore, the fact that the claims recite several species of antimicrobial agents optionally in combination with additional therapeutic agents would not necessarily place a serious burden on the Examiner to search the art and to examine the entire application on the merits, even though it may include claims to independent or distinct inventions. (MPEP § 803) Applicants respectfully request withdrawal of the restriction requirement with respect to the species of antimicrobial agent and additional therapeutic agent.

## CONCLUSION

Applicants respectfully request reconsideration of this application, withdrawal of the restriction requirements, and allowance of all application claims.

Attached hereto is a marked-up version of the changes made to claims by the current amendments. The attached page is captioned "Version With Markings to Show Changes Made".

Respectfully submitted,

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**Version With Markings to Show Changes Made**

1. A topical oral composition for treating and preventing oral cavity diseases in human and animal subjects and thereby promoting whole body health in said human[s] and animal[s] subjects, said composition comprising a safe and effective amount of an antimicrobial agent and a pharmaceutically acceptable oral carrier, wherein said antimicrobial is selected from the group consisting of stannous ion agent; triclosan; triclosan monophosphate; chlorhexidine; alexidine; hexetidine; sanguinarine; benzalkonium chloride; salicylanilide; domiphen bromide; cetylpyridinium chloride (CPC); tetradecylpyridinium chloride (TPC); N-tetradecyl-4-ethylpyridinium chloride (TDEPC); octenidine; delmopinol; octapinol; nisin; zinc ion agent; copper ion agent; essential oils; furanones; bacteriocins; analogs and salts thereof; and mixtures thereof.

2. A topical oral composition [for promoting whole body health in humans and other animals] according to Claim 1, wherein said antimicrobial is selected from the group consisting of stannous ion agent, triclosan, triclosan monophosphate, chlorhexidine, domiphen bromide; cetylpyridinium chloride (CPC), zinc ion agent, copper ion agent, essential oils, and mixtures thereof.

3. The topical composition of claim 1, further comprising one or more additional therapeutic agents selected from the group consisting of: anti-inflammatory agents, H2-antagonists, metalloproteinase inhibitors, cytokine receptor antagonists, lipopolysaccharide complexing agents, tissue growth factors, immunostimulatory agents, cellular redox modifiers, analgesics, hormones, vitamins, and minerals.

4. The topical composition of Claim 3, wherein said additional therapeutic agent is selected from the group consisting of augmentin, amoxicillin, tetracycline, doxycycline, minocycline, metronidazole; aspirin, ketorolac, flurbiprofen, ibuprofen, naproxen, indomethacin, ketoprofen, piroxicam, meclofenamic acid, cimetidine, ranitidine, famotidine, roxatidine, nizatidine, mifentidine, iodine, sulfonamides, mercurials, bisbiguanides, phenolics, neomycin, kanamycin, clindamycin, eugenol, hydrocortisone, methotrexate, levamasole, strontium chloride, potassium nitrate, sodium fluoride, peppermint oil, chlorophyll, immunoglobulin, antigens, lidocaine, benzocaine, amino acids, essential fats, vitamin C, α-tocopherol, Co-enzyme Q10, PQQ, Vitamin A, folate, N-acetyl cysteine, gallic acid, butylated hydroxytoluene, polymyxin, urea peroxide, hydroxamic acid derivatives, phosphinic acid amides, and mixtures thereof.

5. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects,

comprising topically administering to said subjects' oral cavity, a composition according to Claim 1.

6. The method of Claim [4] 5 wherein said composition is in a form selected from a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, and a pet chew product.

7. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects, comprising topically administering to said subjects' oral cavity, a composition according to Claim 3.

8. A method for treating and preventing oral cavity diseases in human and animal subjects and thereby promoting whole body health in said human and other animal subjects, comprising topically administering to said subjects' oral cavity a composition comprising
   a) a safe and effective amount of an antimicrobial agent selected from the group consisting of stannous ion agent, triclosan, triclosan monophosphate, chlorhexidine, domiphen bromide; cetylpyridinium chloride (CPC), zinc ion agent, copper ion agent, essential oils, and mixtures thereof;
   b) a safe and effective amount of an additional therapeutic agent selected from the group consisting of anti-inflammatory agents, H2-antagonists, metalloproteinase inhibitors, cellular redox modifiers, and mixtures thereof; and
   c) a pharmaceutically-acceptable topical, oral carrier.